

Remarks

Claims 1, 5-7, 9-13, 15, and 16 remain in this application. Claim 1 is amended to replace "consisting essentially of" back to "comprising." Claim 1 is further amended to state that after the separated precipitate is washed with acetone, acetone is removed from said precipitate by vacuum filtering. Support for this amendment can be found, *inter alia*, in canceled claim 4. Claim 1 is further amended to state that after a retentate is obtained by ultrafiltration, the retentate is dried to obtain the Bowman-Birk Inhibitor concentrate. Support for this amendment can be found, *inter alia*, in canceled claim 14. Claims 4 and 14 are canceled with this amendment. Claims 2-4, 8, 14, and 17-20 are all of the canceled claims.

Response to the Objection Under 37 CFR 1.75 (c)

Claims 4 and 14 are objected to under 37 CFR 1.75 (c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form. Applicant has amended claim 1 to replace "consisting essentially of" with "comprising." Further, Applicant has canceled claims 4 and 14. Reconsideration and withdrawal of this ground of objection is respectfully requested.

Response to the Rejection Under 35 §USC 112

Claims 4 and 14 are rejected under 35 §USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant has amended claim 1 to replace "consisting essentially of" with "comprising." Further, Applicant has canceled claims 4 and 14. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

Response to the Rejection Under 35 §USC 103 (a)

Claims 1, 5-7, 9-13, 15, and 16 are rejected under 35 §USC 103 (a) as obvious over US Patent No. 5,505,946 ('946).

In the December 8, 2005 amendment, in arguing the 103 rejection, Applicant's representative stated that the present invention uses two acetone extraction steps. This is erroneous. Applicant's claim 1 employs one acetone extraction step and one acetone washing step.

A total of 5 embodiments are outlined in '946 beginning at col. 4, line 46 to col. 5, line 35. In the first 4 embodiments it is necessary to generate either a crude BBI concentrate (CBBIC) or a semi-crude BBI concentrate (SCBBIC). The CBBIC or SCBBIC are prepared from hexane defatted soybeans wherein the soy protein is aqueous extracted from the hexane defatted soybeans. Added to this protein extract is an acid that generates a slurry of a soy protein precipitate as a curd. The remaining phase is a liquor that when separated as a centrate, is defined as the acid extracted solubles. Additional water is added to the centrate and the centrate is ultrafiltered to obtain a CBBIC. When the ultrafiltered step is repeated, a SCBBIC is obtained.

In the first embodiment of '946 beginning at col. 4, line 60, added to either the CBBIC or SCBBIC is acetone to produce a BBI precipitate. After settling and decanting, the precipitate is dried, reslurried, filtered and lyophilized to produce a BBI concentrate.

In the second embodiment of '946 beginning at col. 4, line 66, added to SCBBIC is acetone to produce a BBI precipitate. The BBI precipitate is worked up as per the first embodiment with the exception that the filtered precipitate is spray dried rather than lyophilized.

In the third embodiment of '946 beginning at col. 4, line 8, CBBIC is prepared. Water is added and the contents are spray dried to produce a BBIC. No acetone is employed.

In the fourth embodiment of '946 beginning at col. 4, line 17, SCBBIC is prepared. The contents are spray dried to produce a BBIC. No acetone is employed

In the fifth embodiment of '946, beginning at col. 5, line 22, acid extracted soybean solubles are prepared. Acetone is added to form a precipitate. The precipitate is resuspended in water and centrifuged. Again acetone is added to the second supernatant to again precipitate BBI. The precipitate is dried to produce a BBI product. No ultrafiltration is employed.

Combining any of the above embodiments does not make the present invention as obvious. The present invention is outlined below.

Acid extracted solubles are prepared. Acetone is added to the acid extracted solubles to form a precipitate. The precipitate is separated and the separated precipitate is washed with acetone to form a washed precipitate. Acetone is removed from the washed precipitate by vacuum filtering to form a vacuum separated precipitate. The vacuum separated precipitate is dissolved in water to form an aqueous solution. The aqueous solution is subjected to ultrafiltration to form a retentate and a permeate. The retentate is dried to form a Bowman-Birk Inhibitor concentrate.

None of the '946 embodiments employ an acetone washing of the BBI precipitate, as per the present invention. None of the '946 embodiments employ an ultrafiltration step of the dissolved BBI precipitate, as per the present invention. Picking and choosing any of the above '946 steps from any of the above '946 embodiments does not make the present invention obvious.

Turning now to the examples of '946, it is noted that Examples 1-7 are directed to the preparation of BBIC. Example 2 exemplifies the first embodiment. Example 3 exemplifies the second embodiment. Example 4 exemplifies the third embodiment. Example 5 exemplifies the fourth embodiment. Example 6 exemplifies the third embodiment. Example 7 exemplifies the fifth embodiment.

This leaves Example 1. Soy flour and 60% aqueous ethanol are combined to form a slurry. The slurry is permitted to settle and the supernatant is drawn off and is filtered. Acid is added to the supernatant to a pH of 5.3. While it is not taught, it is understood by one skilled in the art that adding acid to a protein extract causes the formation of curds and whey. The whey is the acid extracted solubles. After acid addition, it is stated in Example 1 that acetone is added at this point. The addition of acetone to the acid extracted solubles causes a precipitate of crude BBI to form. This BBI precipitate is present with the curds from the acid addition. Further, acetone does not dissolve the curds. Example 1 further states that the precipitated solids (curds and crude BBI) is permitted to settle and that the supernatant is filtered and the precipitate (curds and crude BBI) are combined with any precipitate from the filtered supernatant. The solids

(curds and crude BBI) are resolubilized. The BBI will go into solution but not the curds. The liquid part (BBI in water) is ultrafiltered and the retentate is freeze-dried to give a BBIC.

There is no teaching in Example 1 employing an acetone washing of the BBI precipitate, as per the present invention. None of the '946 embodiments employ an acetone washing step, as per the present invention. Picking and choosing any of the above steps from Example 1 with any of the above '946 embodiments does not make the present invention obvious.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. The Office has clearly failed to meet its burden under (1) and/or (2) above, since the embodiments and the examples of the prior art reference fail to teach or suggest all of the claim limitations of Applicant's claim 1, as amended and further that there is no motivation by one of ordinary skill in the art for employing limitations present in Applicants' claim 1 not present in the prior art reference. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

For the foregoing reasons, it is submitted that the present claims are in condition for allowance. The foregoing remarks are believed to be a full and complete response to the outstanding office action. Therefore favorable reconsideration and allowance are respectfully requested. If for any reason the Examiner believes a telephone conference would expedite the prosecution of this application, it is respectfully requested that she call Applicant's representative at 314.659.3218.


SP-1309 US
Serial No.: 10/693,433
July 21, 2006

Page 8

If any additional fees are due in connection with the filing of this document, the Commissioner is authorized to charge those fees to our Deposit Account No. 50-0421.

Respectfully submitted,
SOLAE, LLC

Date: July 21, 2006


James L. Cordek
Registration No. 31,807

PO Box 88940
St. Louis, MO 63188
314.982.2409